North of Scotland Research Ethics Committee
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net

19 January 2016

Ms Heather Clark
University of Aberdeen
Dugald Baird Centre
Aberdeen Maternity Hospital
ABERDEEN
AB25 2ZL

Dear Ms Clark

Title of the Database:	**Aberdeen Children of the 1950s version 3**
REC reference:	**16/NS/0004**
IRAS project ID:	**194680**

The Research Ethics Committee reviewed the above application at the meeting held on 14 January 2016. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Sarah Lorick, nosres@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation, subject to the conditions specified below.

This application was for the renewal of a Research Database application. The previous REC Reference number for this application was 11/S0802/6.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Research governance

A copy of this letter is being sent to the R&D office responsible for NHS Grampian.

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research databases.

Summary of discussion at the meeting

The Committee thanked you for submitting the renewal of ethical approval for the research database. The application was very clear and the Committee was satisfied with the demonstration of custodianship of data.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Research Database Renewals

The Research Database has been renewed for a further five years from the end of the previous five year period. The previous five year period ran from 17 January 2011 to 17 January 2016.

This Research Database may be renewed for further periods of five years at a time by following the process described in the above paragraph.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper: REC Covering Letter		04 December 2015
IRAS Checklist XML: Checklist 09.12.2015		09 December 2015
Application Form for Data Access	2	15 May 2013
Heather Clark CV		02 December 2015
Annex C - Variable List	1	01 September 2010
Annex E - Ethical Permissions Summary	1	01 August 2010
Participant consent form: Annex B - Consent Form from 2001 Questionnaire	Final	18 June 1999
Participant information sheet (PIS): Annex A - Information Sheet from 2001 Questionnaire	Final	18 June 1999
Protocol for management of the database	1.3	04 December 2015
REC Application Form: RD Form 09.12.2015	194680/8894 07/9/435	09 December 2015

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and

the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/NS/0004	**Please quote this number on all correspondence**

Yours sincerely

Mr Gary Cooper
Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
	Approval conditions
Copy to:	NHSG R&D Department Professor Philip Hannaford

North of Scotland Research Ethics Committee (2)

Attendance at Committee Meeting on 14 January 2016

Committee Members:

Name	Profession	Present	Notes
Mr Gary Cooper	Lay Member - Chair and Quality Assurance Manager	Yes	
Dr Dolapo Ayansina	Statistician	Yes	
Dr Rebecca J Barr*	Senior Research Fellow	Yes	
Mr Russell Brinklow	Community Psychiatric Nurse	No	
Dr Hanne Bruhn	Lay Member - Research Fellow - Psychology	No	
Dr Jennifer Caldwell	Senior Lecturer in Occupational Therapy	No	
Mrs Ann Conroy	Retired Midwife	Yes	
Dr Ian Fleming	Research Fellow	Yes	
Professor Helen Galley*	Chair of Anaesthesia & Intensive Care	Yes	
Dr Georgina Hold	Vice-Chair & Senior Lecturer - Gastroenterology	No	
Dr Petr Kalous	Consultant Neonatologist	No	
Dr Kirsty Kiezebrink	Lecturer	Yes	
Mrs Kathryn McMullan	Retired Clinical Pharmacist	No	
Mrs Sophie Welch	Coach Practitioner	No	

*co-opted from Committee (1)

Also in attendance:

Name	Position (or reason for attending)
Miss Karen Gauld	Ethics Administrator
Dr Sally Kilburn	Scientific Officer
Ms Sarah Lorick	Assistant Ethics Co-ordinator